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10/521,176

01/14/2005

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EXAMINER

BHAT, NARAYAN KAMESHWAR

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/521,176 | Applicant(s) OKAMURA ET AL. | |
| | Examiner Narayan K. Bhat | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is written in reply to applicant's correspondence filed August 1, 2007. Claims 1 and 6 were amended. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

2. Claims 1-16 are pending in this application.
3. Claims 10-16 are withdrawn.
4. Claims 1-9 are under prosecution.

Amendments to Claims

5. Amendments to the claims 1 and 6 have been reviewed and entered.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 is indefinite over the recitation of the term "which substrate is chemically modified" in line 4, is confusing because it is not clear whether the substrate is chemically modified or the electrostatic layer on the substrate is modified or both the substrate and electrostatic layer are chemically modified. Therefore the claim has been

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interpreted broadly to include chemical modification of either substrate or electrostatic layer or both.

9. Claims 2-9 are indefinite because they are dependent on claim 1.

10. Claim 6 is indefinite over the recitation of "any one of claim 1" because there is only one claim 1.

11. Claim 7 is indefinite because it is dependent on claim 6.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-2, 4-6 and 8-9 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Pantano et al (USPN 6,916,541 filed Sept. 7, 2001).

Regarding claim 1, Pantano et al teaches a solid support (Fig. 5, element labeled as glass substrate), having an electrostatic layer for electrostatically attracting nucleic acid molecule (column 5, lines 45-50). Pantano also teaches substrate is chemically

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modified to introduce a functional amine group capable of covalently binding of nucleic acid molecule (column 5, lines 54-63).

Regarding claim 2, Pantano et al teaches that the substrate is diamond (Column 3, lines 24-29).

Regarding claim 4, Pantano et al teaches a solid support wherein the electrostatic layer is composed of an amino group-containing compound (DETA) which covalently binds to the substrate and the amino group containing compound has amino group at the terminus to which the substrate does not bind (Fig. 5).

Regarding claims 5, 8 and 9, Pantano et al teaches a solid support (Fig. 5, substrate labeled as glass substrate) which is obtained by depositing DETA, a compound having an amino group, which is also a carbon compound that introduces functional amino group capable of covalent binding to a nucleic acid molecule (Fig. 5, column 5, lines 41-63, limitation of claim 5) thus immobilizing the nucleic acid molecule on the solid support (limitations of claims 8 and 9).

Regarding claim 6, Pantano et al teaches a solid substrate having unsubstituted amino group capable of covalently binding to a nucleic acid molecule (Fig. 5, column 5, lines 41-63).

The solid support taught by Pantano meets the structural limitations of the claimed product, though they are made by a different process (i.e., the method according to claim 6). Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself (See MPEP § 2113). The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re Thorpe, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985). Claim 6 is drawn to a solid support having a functional group capable of covalently binding nucleic acid molecule (i.e., a product), but is defined by various method steps that produce said product and, as a result, represents a product-by-process claim. Thus, the process limitations do not appear to provide any structural distinction to the claimed invention in accordance with MPEP § 2113.

14. Claims 1 and 3-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz (USPN 6,911,535 filed January 15, 2002).

Previous rejections are maintained.

Regarding claim 1, Schwartz teaches a solid surface (Fig. 1, Panel 4, labeled as 'S'; column 3, lines 28-32) having an electrostatic layer made up of functionalized cationic polymer (Fig. 1, Panel 1, labeled as 'P') conjugated with biomolecule (Fig. 1, Panel 3, labeled as 'BP') and electrostatically attracting said conjugate to the solid surface (Fig. 1, Panel 5, labeled as 'BPS'). Schwartz further teaches that biomolecule is

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nucleic acid (Column 5, line 57). The functionalized cationic polymer-biomolecule conjugate (herein after referred as BP) of Schwartz is the electrostatic layer of the instant claim. Schwartz also teaches that the BP is immobilized on the solid support via electrostatic interaction between the cationic polymer and the solid support (Column 15, lines 38-42) thus teaching a solid support having an electrostatic layer for electrostatically attracting a nucleic acid molecule.

Schwartz teaches a solid support modified with a reactive moiety (Fig. 1, step # 4; solid support labeled as 's', reactive moiety labeled as 'B', column 3, lines 26-35) that is capable of forming a covalent linkage with a biopolymer (Fig. 1, step # 5; labeled as 'BPS', column 3, lines 19-35). Modification of substrate with a reactive moiety, taught by Schwartz is the chemical modification of the substrate to introduce a functional group of the instant claim.

Regarding claim 3, Schwartz teaches BP, i.e., electrostatic layer, include cationic polymer that is poly-l-lysine containing side chain amino group immobilized on the solid support via electrostatic interaction between the cationic polymer and the solid support (Column 15, lines 38-42) thus teaching amino group containing compound, which does not covalently bind to the substrate.

Regarding claim 4, Schwartz teaches BP, i.e., electrostatic layer, include cationic polymer, that is poly-l-lysine, containing side chain amino group functionalized with

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hydrazine derivative containing amino group as well capable of conjugating a oligonucleotide, a biomolecule with the cationic polymer (Fig 4, see the last step).

Schwartz also teaches the covalent binding of BP to the solid support is through 5' hydrazine oligo/ surface CHO/poly-L-lysine (Fig. 5, see the legend and also see row C and lanes 2 & 3; Column 22 & 23, lines 42-67 & 1-14), thus teaching a amino functional group of hydrazine capable of covalently binding to the substrate. Schwartz further teaches that the BP containing cationic polymer with side chain amino group is also immobilized on the solid support via electrostatic interaction between the cationic polymer and the solid support (Column 15, lines 38-42) thus teaching amino group containing compound, in the electrostatic layer which does not covalently bind to the substrate. Thus the teachings of Schwartz encompass the embodiments of said claim.

Regarding claim 5, Schwartz teaches a hydrazine derivative compound having monosubstituted amino group (Fig. 4, Panel 2, see the hydrazine derivative compound in the middle) capable of attaching biomolecules to the cationic polymer, that is, BP (Fig. 4, last step, Column 14 & 15, lines 60-67 & 1-3). Schwartz also teaches aldehyde modified solid support (Column 21, lines 40-46), which is carbon compound on the substrate. Schwartz further teaches immobilization of BP to the aldehyde coated solid surface is via covalently immobilizing BP through 5' hydrazine oligo/ surface CHO/poly-L-lysine (Fig. 5, see the legend, also see row C and lanes 2 & 3; Column 22 & 23, lines 42-67 & 1-14) thus encompassing the embodiments of the said claim.

Regarding claims 6 and 7, Schwartz teaches a solid support modified with a reactive moiety (Fig. 1, step # 4; solid support labeled as 's', reactive moiety labeled as 'B', column 3, lines 26-35) that is capable of forming a covalent linkage with a biopolymer (Fig. 1, step # 5; labeled as 'BPS', column 3, lines 19-35). Schwartz also teaches that reactive moiety is an amino group (column 14, lines 35-50) comprising of aryl amino group (column 9, line 15).

The solid support taught by Schwartz meets all of the structural limitations of the claimed product, though they are made by a different process (i.e., the method according to claim 6). Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself (See MPEP § 2113). The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re Thorpe, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985). Claim 6 is drawn to a solid support having a functional group capable of covalently binding nucleic acid molecule (i.e., a product), but is defined by various method steps that produce said product and, as a result, represents a product-by-process claim. Thus, the process limitations do not appear to provide any structural distinction to the claimed invention in accordance with MPEP § 2113.

Regarding claims 8 and 9, Schwartz teaches the nucleic acid molecule is oligonucleotide, that is, DNA (Column 4, lines 9-13) immobilized on a solid support (Column 4, lines 45-50).

Response to Remarks from the applicants

Art Rejections

Claim Rejections Under 35 U.S.C. § 102(b)

15. Applicant's arguments filed August 1, 2007, with respect to rejection as being anticipated by Chrisey" have been fully considered and are persuasive. The previous rejections of claims 1, 2, 5, 8 and 9 have been withdrawn.

16. Applicant's arguments filed on August 1, 2007 with respect to rejections of claims 1, 3-5, 8 and 9 as being anticipated by Schwartz have been fully considered but they are not persuasive for the following reasons.

17. Applicant argues that "Schwartz disclose that it is the polymer binds to the substrate, not the biomolecule" and that argument is not found persuasive because Schwartz teaches a covalent binding of biomolecule to the substrate via polymer (Fig. 1, step 5, covalent binding to the substrate via 'B' reactive molecule to group 'A' on the polymer and covalent linkage of group 'A' on the polymer to the biomolecule, column 3, lines 10-35).

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself (See MPEP § 2113). The patentability of a product does not depend on its method of production. If the

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product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re Thorpe, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985). Schwartz teaches a solid support having a functional group capable of covalently binding nucleic acid molecule (i.e., a product), but are defined by various method steps that produce said product and, as a result, represents a product-by-process claim. Thus, the process limitations do not appear to provide any structural distinction to the claimed invention in accordance with MPEP § 2113.

18. Applicant argues that "the surface of the substrate that is chemically modified and Schwartz teaches that the polymer is chemically modified" and those arguments are not found persuasive because, Schwartz explicitly teaches chemical modification of a substrate by the same reactive moiety as incorporated in the biomolecule (Fig. 1, step 4, surface modification with reactive group 'B', column 3, lines 28-35, covalent linkage of biopolymer to the substrate, Fig. 1, steps 1-5, column 3, lines 10-35).

For all of the reasons listed above and as described in detail in this office action, Schwartz teaches the structural features of a biochip substrate recited in the claims and therefore applicant's arguments are not found persuasive.

Double Patenting

19. Provisional obviousness-type double patenting rejection of claims 1-5 and 8-9 of 10/521,176 application over claims 1-3 and 13-17 of copending Application No.

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10/182,434 has been withdrawn in view of filing and approval of a terminal disclaimer filed on 8/01/2007.

Conclusion

20. No claim is allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

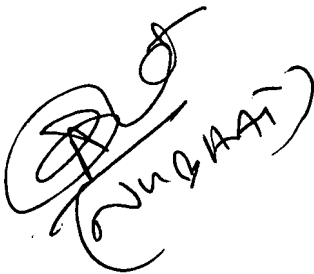
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

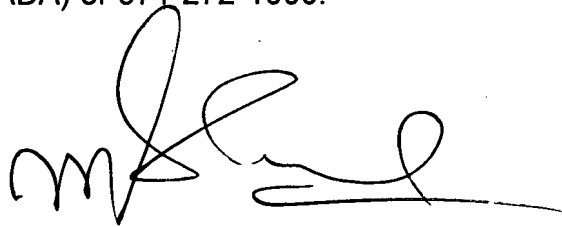
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Narayan K. Bhat, Ph. D.

Examiner

Art Unit 1634

**RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER**